K052223

OCT - 6 2006

510(k) Summary

Date Prepared: October 4, 2006

Applicant: Beckman Coulter, Inc.
Immunodiagnostics Development Center
1000 Lake Hazeltine Drive
Chaska, MN 55318

Contact Person: Lynn Weist, Staff Regulatory Specialist

Trade Name: Access® EPO Assay

Product Classification and Code: Device Class - II

Classification Code – GGT (EPO Assay) and JIT (Calibrators)

Predicate Devices: K936016 - Quantikine IVD Erythropoietin ELISA Kit - R & D Systems, Inc.

K983203- IMMULITE EPO - Diagnostic Products Corp.

K980737 - Nichols Advantage Chemiluminescent Erythropoietin Immunoassay - Nichols Institute Diagnostics

K992799 – Sangui Bio Tech, Inc. EPO [Erythropoietin] ELISA Kit

Device Description: The Access® EPO assay consists of the reagent pack and calibrators. Other items needed to perform the assay include the Access substrate and wash buffers.

Intended Use: The Access EPO assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of erythropoietin levels in human serum and plasma (heparin) using the Access Immunoassay Systems. This assay is intended as an aid in the diagnosis of anemias and polycythemias. With the advent of the administration of recombinant erythropoietin as a biologic therapy to increase red blood cell mass, an erythropoietin assay may be used also to aid in the prediction and monitoring of response to recombinant erythropoietin treatment in persons with anemias.

The Access EPO calibrators are intended to calibrate the Access EPO assay for the quantitative determination of EPO levels in human serum and plasma (heparin) using the Access Immunoassay Systems.

Comparison of Technological Characteristics:

Attribute	Access EPO	R&D Systems	DPC	Nichols	Sangui Bio Tech
Assay Type / Format	2-site simultaneous immunometric (sandwich) chemiluminescent	ELISA	2-site sequential enzyme immunometric (sandwich) chemiluminescent	2-site simultaneous immunometric (sandwich) chemiluminescent	2-site simultaneous immunometric (sandwich) assay (ELISA)
Composition	Paramagnetic particles coated with goat anti-mouse IgG: mouse anti-recombinant human EPO monoclonal antibody, BSA, sodium azide and ProClin 300. Chicken anti-recombinant mouse EPO alkaline	Microplate – polystyrene microplate coated with mouse monoclonal antibody against recombinant human EPO. Conjugate – anti-EPO polyclonal (rabbit) antibody: horseradish peroxidase conjugate w/ thimerosal as a	Solid phase – Polystyrene bead coated with an anti-ligand derived from streptavidin. Reagent – ligand-labeled murine monoclonal anti-EPO antibody with preservative. Alkaline phosphatase conjugated to goat polyclonal anti-	Streptavidin coated magnetic particles in a buffer containing goat, rabbit and mouse gamma globulin with sodium azide and ProClin 300. Acridinium ester-labeled mouse monoclonal antibody to human EPO in a buffered protein solution with antimicrobial	Carboxyl-terminal mouse monoclonal antibody & an affinity purified region-restricted amino-terminal sheep antibody. Solid phase coated with avidin. Capture antibodies are coupled with biotin. Horseradish peroxidase labeled Tag antibody.

510(k) Summary

Comparison of Technological Characteristics:

(continued)

Attribute	Access EPO	R&D Systems	DPC	Nichols	Sangui Bio Tech
Composition (continued)	phosphatase (bovine) conjugate, BSA, sodium azide and ProClin 300. TRIS saline buffer containing BSA, proteins (chicken, bovine, mouse), sodium azide and ProClin 300	preservative.	EPO antibody in buffer, with preservative.	agents. Biotin labeled mouse monoclonal antibody to human EPO in a buffered protein solution, with sodium azide and ProClin 300.	
Measuring Range / Reportable Range	0.6 – 750 mIU/mL	0-200 mIU/mL	0-200 mIU/mL	5-700 mU/mL	Unknown
Standardization	WHO 2nd IRP 67/343	WHO 2nd IRP 67/343	WHO 2nd IRP 67/343	WHO 1st IS 87/684	Unknown

Summary of Performance Studies:

Precision: The assay exhibits total precision of ≤ 10% CV at EPO concentrations > 3mIU/mL. Assay precision was tested at concentrations from approximately 9 to 475 mIU/mL. The within-run imprecision ranged from 1.8% CV to 8.7% CV. Total imprecision ranged from 2.6% CV to 8.7% CV.

Analytical Sensitivity: The lowest detectable level of EPO distinguishable from zero (Access EPO Calibrator S0) is ≤0.6 mIU/mL.

Dilution Recovery (Linearity): Dilution recovery studies were performed by diluting multiple human serum and plasma (heparin) samples at various levels with Access EPO Calibrator S0. Sample mean recovery values for all serum and plasma samples, were within the range of 100 ± 15%.

Methods Comparison: Internal and external site comparison studies run with both the Access EPO and RDS Quantikine ELISA assays demonstrated acceptable agreement and the following statistical data.

Internal Site Study: Slope of 1.0511, intercept of –1.3595, and correlation coefficient (r) of 0.988. For this study N=103 with an EPO concentration range of approximately 3 to 182 mIU/mL.

External Site Study: Slope of 1.1216, intercept of –2.4168, and correlation coefficient (r) of 0.995. For this study N=113 with an EPO concentration range of approximately 3 to 193 mIU/mL.

Analytical Specificity: There was no significant interference from therapeutic drugs or similar compounds in the Access EPO assay. In addition, there was no significant interference from potential sample contaminants (total protein, bilirubin, hemoglobin, and triglycerides).

Stability: EPO reagents are stable for 28 days after opening and calibrators are stable for 90 days after opening. The calibration curve is stable for 28 days.

Conclusion:

The EPO Assay and EPO Calibrators on the Access Immunoassay Systems is substantially equivalent to the predicates for the measurement of EPO in human serum and plasma.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT - 6 2006

Ms. Lynn Weist
Staff Regulatory Specialist
Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, MN 55318

Re: k052223
Trade/Device Name: Access® EPO Assay
Regulation Number: 21 CFR § 864.7250
Regulation Name: Erythropoietin Assay
Regulatory Class: II
Product Code: GGT, JIT
Dated: August 30, 2006
Received: August 31, 2006

Dear Ms. Weist:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052223

Device Name: Access® EPO Assay

Indications for Use:

The Access® EPO assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of erythropoietin levels in human serum and plasma (heparin) using the Access Immunoassay Systems. This assay is intended as an aid in the diagnosis of anemias and polycythemias. With the advent of the administration of recombinant erythropoietin as a biologic therapy to increase red blood cell mass, an erythropoietin assay may be used also to aid in the prediction and monitoring of response to recombinant erythropoietin treatment in persons with anemias.

The Access EPO calibrators are intended to calibrate the Access EPO assay for the quantitative determination of EPO levels in human serum and plasma (heparin) using the Access Immunoassay Systems.

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K052223

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)